Taking Vedolizumab in Pregnancy Did Not Increase the Risk of Birth Defects or Adverse Pregnancy Outcomes

LA JOLLA, CA – Vedolizumab (sold under the trade name Entyvio®) is a medication that is used to treat Crohn's disease and ulcerative colitis, which are two forms of inflammatory bowel disease (IBD). For women who became pregnant while taking vedolizumab, there are limited data on whether this medication could affect the pregnancy and the developing baby. Our study sought to examine this question by evaluating the safety/risk of vedolizumab use in pregnant women who were participating in MotherToBaby Pregnancy Studies.

What did we study? From 2015 to 2022, we enrolled 275 pregnant women in the United States and Canada; 99 of the women had IBD and reported taking vedolizumab sometime during their pregnancy, 76 women had IBD but were being treated with other biologic medications, and the remaining 100 women did not have IBD and were not exposed to vedolizumab or other biologic medications.

We interviewed the mothers up to three times during their pregnancy and once at the end of their pregnancies. We also collected information from the medical records of both mom and baby. Finally, a subset of the babies was examined by one of our study doctors. We then compared the three groups of women by looking at several pregnancy and birth outcomes, including pregnancy loss, preterm birth, and birth defects.

What did we find? We found no meaningful differences in the rates of pregnancy loss, preterm birth, or birth defects between the groups. There were also no meaningful differences between the groups on infant growth measures at birth and at 1 year of age.

What's the takeaway? Taking vedolizumab in pregnancy did not increase the chance of birth defects or other adverse pregnancy outcomes. Our study provides additional reassuring evidence for women with IBD who take vedolizumab during pregnancy.

Reference:

Chambers CD, Johnson DL, Luo Y, Xu R, Adam MP, Braddock SR, Jones KL; OTIS Collaborative Research Group. Birth Outcomes in Women Who Have Taken Vedolizumab in Pregnancy: Results from the Vedolizumab Pregnancy Exposure Registry. Am J Gastroenterol. 2025 Jun 11. doi: 10.14309/ajg.0000000000003593. Epub ahead of print. PMID: 40498121.

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Questions? Call 866.626.6847 | Text 855.999.3525 | Email or Chat at MotherToBaby.org.

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Taking Vedolizumab in Pregnancy Did Not Increase the Risk of Birth Defects or Adverse Pregnancy Outcomes

MotherToBaby is the Leading National Resource on Exposures during Pregnancy and Breastfeeding

BRENTWOOD, TN – The non-profit Organization of Teratology Information Specialists (OTIS), which provides the MotherToBaby free service, receives new funding aimed at enhancing partnerships to address birth defects, infant disorders and related conditions, and the health of pregnant and postpartum people. The grant is supported by the Centers for Disease Control and Prevention (CDC).

The funding is a five-year award beginning October 1, 2023. “This remarkable funding is a testament to our tireless dedication to staying ahead of the curve when it comes to diseases, infections, and empowering the public with the latest information,” said Alfred Romeo, RN, PhD, President of MotherToBaby. “We are thrilled to collaborate with numerous organizations to amplify the impact of our vital work,” he added.

Great strides will be made under this grant, including collecting and disseminating data, developing and distributing data-driven resources, forging valuable partnerships, and fostering community engagement to raise awareness of the invaluable services provided by MotherToBaby.

“This support is a game-changer, enabling us to further equip pregnant and breastfeeding individuals with crucial information, especially during health crises like the recent COVID-19 pandemic,” Romeo emphasized. “The partnerships we build will help us navigate the next emerging issue affecting people who are pregnant and breastfeeding.”

MotherToBaby provides information on exposures, like medications, vaccines, diseases, herbal supplements, occupational exposures and more before and during a pregnancy as well as while breastfeeding. The service is provided through its no-cost helpline 866-626-6847, texting service 855-999-3525 and website www.MotherToBaby.org, where the public can live chat, e-mail an expert or browse a library of fact sheets in English and Spanish. Additionally, MotherToBaby hosts LactRx, a free app providing current information on the use of medications, vaccines, diagnostic agents, and drugs of misuse during breastfeeding. LactRx is available for iPhone

and Android.

More about OTIS and MotherToBaby

The Organization of Teratology Information Specialists (OTIS) is a professional scientific society made up of individuals engaged in assessing and evaluating risks to pregnancy and breastfeeding from environmental exposures. Members include, but are not limited to, specialists in the fields of obstetrics and gynecology, pediatrics, genetics, dysmorphology, perinatal epidemiology, teratology, behavioral teratology, pharmacy, genetic counseling, nursing, midwifery, maternal and child health, public health, and includes experts that provide MotherToBaby services and researchers that conduct MotherToBaby Pregnancy Studies. To learn more about MotherToBaby and OTIS, please visit www.MotherToBaby.org.

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Taking Vedolizumab in Pregnancy Did Not Increase the Risk of Birth Defects or Adverse

Pregnancy Outcomes

Non-Profit's Expertise Recognized as Leading Resource on Exposures during Pregnancy and Breastfeeding

September 21, 2022

BRENTWOOD, TN – The non-profit Organization of Teratology Information Specialists (OTIS) through its public-facing service, MotherToBaby, are now contributors to the prestigious National Library of Medicine (NLM) where more than 250 of its bilingual (English/Spanish) evidence-based fact sheets can be found on medications, vaccines, diseases, herbal supplements, occupational exposures and more during pregnancy and breastfeeding.

MotherToBaby provides information on exposures before and during a pregnancy as well as breastfeeding traditionally through its no-cost helpline 866-626-6847, texting service 855-999-3525 and website www.MotherToBaby.org, where the public can live chat or e-mail an expert. "This is just one more way we can ensure pregnant people and healthcare providers can have access to reliable, up-to-date, research-based information so they can make better informed decisions during the child-bearing journey or in cases of adoption," said Christina Chambers, PhD, MPH, MotherToBaby Past President and UC San Diego professor of pediatrics. "Being a part of the NLM is a testament to the reliability of our resources. We are honored to be contributors."

For more than 200 years, "the National Library of Medicine has been a partner for biological discovery, clinical care decision-making and healthcare choices in everyday living," according to its website. The NLM includes health information tools and biomedical literature, such as PubMed. The MotherToBaby Fact Sheets through the NLM can be accessed through public and hospital libraries as well as in schools and clinics. It's also available at the following link: https://www.ncbi.nlm.nih.gov/books/NBK582980/

More about OTIS and MotherToBaby

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Taking Vedolizumab in Pregnancy Did Not Increase the Risk of Birth Defects or Adverse Pregnancy Outcomes

Adopted by the OTIS Board in June 2022

The Organization of Teratology Information Specialists (OTIS) opposes laws that prevent people from making informed reproductive choices, or that seek to prevent or criminalize healthcare professionals who inform patients of scientific knowledge or reproductive options. OTIS will continue to provide confidential, evidence-based, scientifically accurate and unbiased information about exposures before and during pregnancy that allows people who are pregnant or who could become pregnant to make informed reproductive choices.

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Taking Vedolizumab in Pregnancy Did Not Increase the Risk of Birth Defects or Adverse Pregnancy Outcomes

Adopted by the OTIS Board in March 2022

The Organization of Teratology Information Specialists (OTIS) stands in solidarity with the Ukrainian people and our friends and colleagues in Ukraine. We have proudly provided education and training on teratogens in Ukraine since 2003 and helped our Ukrainian colleagues to establish their own Teratology Information Service in 2017. We feel a great kinship to the many people our various members have worked with over the years and it is greatly distressing for us to see the current events unfold.

As a professional organization comprised of leading healthcare professionals in the area of teratology, or birth defects, we hope for the safety and health of pregnant and breastfeeding individuals and their children as they deal with the difficult situation in Ukraine and neighboring countries. We are concerned about the increased risk of harmful pregnancy exposures related to warfare, the negative psychological impacts of conflict, the interruption of access to maternal healthcare, and the effects these conditions may have on generations to come. We hope a healthy future is restored immediately for all who are impacted.

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